Remarks:

Reconsideration of the application in view of the above following remarks is requested. Claims 1-2, and 4-14 are now in the case. Claim 3 has been canceled. Applicants assert that the present amendment adds no new matter.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

THE 35 U.S.C. §101 AND §112, FIRST PARAGRAPH REJECTIONS

The Office Action maintains the rejection of Claims 1-2, and 4-14 under 35 USC §101 as not supported by either a specific and substantial asserted utility or well established utility. In particular, it is asserted that the invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance.

Applicants respectfully traverse this rejection. To be considered useful under 35 U.S.C. §101, an invention must have a specific, substantial and credible utility. It is well established that "when a properly claimed invention meets at least one stated objective, utility under §101 is clearly shown." (Raytheon Co. v. Roper Corp., 724 F.2d 951, 958 (CAFC 1983)). That is, only a single utility for an invention needs to be disclosed in a patent application to satisfy the 35 U.S.C. §101 utility requirement.

The present invention bears utility based on its homology to IL-17RD (SEF).

Applicants have submitted a specific and substantial utility for the present invention. The polynucleotides of the present invention encode a receptor, Zcytor18, that "can be used to modulate the immune system by binding Zcytor18 ligand, and thus, preventing the binding of Zcytor18 ligand with endogenous Zcytor18 receptor." Page 69, lines 12-14. Applicants point out that preventing the binding of Zcytor18 ligand with endogenous Zcytor18 receptor "can be used to inhibit cell proliferation associated with, for example psoriasis or the growth of a tumor (*e.g.*, a melanoma). Page 69, lines 15-16.

However, the Patent Office has suggested that the mere fact that Zcytor18 is a member of the interleukin-17 (IL-17) receptor family is not persuasive to impute substantial and credible utility to Zcytor18. The Patent Office alleges that it is unclear

what ligand the Zcytor18 will bind to. **Applicants strongly disagree with this characterization of the present invention:** Zcytor18 is not merely a member of IL-17 receptor related family; rather, Zcytor18 is a member of the IL-17 receptor related family that bears significant homology with IL-17RD (SEF). One having ordinary skill in the art would presume that Zcytor18 shares binding activity of SEF. The Patent Office suggests that Zcytor18 is unlikely to share the binding activity of (SEF) because, although Zcytor18 is 97.6% homologous to SEF, it has an extra 14 amino acid residues at amino acid residues 43-56 and two other residues vary. These differences are because SEF is a splice variant of Zcytor18. See for example, page 3, lines 18-19 of the Specification: "A splice variant of Zcytor18 lacks amino acid residues 43 to 56 of SEQ ID NO:2."

In spite of these differences, one having ordinary skill in the art would still presume that Zcytor18 and SEF retain the same ligand binding properties. There is extensive evidence of alternative splicing among the receptors of the IL-17 family. Moseley et al., Cytokine Growth Factor Reviews, 2003 14(2):155-174, 157. For example, IL-17RH1 and IL-17RL are splice variants that share a high degree of variation; however in spite of that variation, according to Moseley et al., IL-17RH1 and IL-17RH "presumably retain their ligand binding properties." *Id* at 157-158. One having ordinary skill in the art would likewise presume that SEF and Zcytor18 retain the same ligand binding properties. SEF binds to the IL-17D ligand. Moseley et al., Cytokine Growth Factor Reviews, 2003. Accordingly, one having ordinary skill in the are would presume that, like SEF, Zcytor18 will bind to the IL-17D ligand.

The present invention bears utility for detecting gross chromosomal aberrations and diagnosing corresponding diseases.

Applicants have submitted a second specific, substantial, and credible utility. The "Zcytor18 gene resides in human chromosome 3p14.3" See page 3, line 2. Therefore, "nucleic acid probes that encode Zcytor18, or a fragment thereof, can be used to detect gross aberrations in chromosome 3"; and thereby, the nucleic acid probes can be used to detect a correlating disease a correlating disease. See page 64, lines 27-29. For example, the Specification lists several diseases associated with aberrations of chromosome 3, including: acute myelocytic leukemia, chronic leukemia, neuroendocrine

cancer, polyclonal B-cell lymphocytosis, and renal cell carcinoma. See page 64, lines 29-34. The 3p14.3 region is also associated with various other diseases and disorders including Wernicke-Korsakoff Syndrome, and Bardet-Biedl Syndrome 3. See page 64, lines 34-35.

Thus, a nucleic acid probe that encodes Zcytor18 can be used to detect gross aberrations in chromosome 3 and so diagnose a corresponding disease, including acute myelocytic leukemia, chronic leukemia, neuroendocrine cancer, polyclonal B-cell lymphocytosis, or renal cell carcinoma.

By the preceding, Applicants have presented the Patent Office with two specific, substantial, and credible utilities for the present invention: 1) The present invention may be used to inhibit the binding of the Zcytor18 ligand with the endogenous Zcytor18 receptor in order to inhibit cell proliferation associated with, for example, psoriasis or the growth of a tumor; and 2) the present invention may be used to detect gross aberrations in chromosome 3 in order to diagnose a corresponding disease. Accordingly, Applicants respectfully request that the 35 U.S.C. §101 utility rejection of Claims 1-14 be withdrawn.

Conclusion

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

The requisite fee for Extension of Time is enclosed. It is believed that no other fee is due. However, in the event that another fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,

Shelby J. Walker
Registration No. 45,192

Enclosures:
Petition and Fee for Extension of Time
Amendment Fee Transmittal
Notice of Appeal

Customer No. 10117
ZymoGenetics, Inc.